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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,549	10/18/2004	Takahide Ohishi	Q102803	9316

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EXAMINER	
HOBBS, LISA JOE	

ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,549	OHISHI ET AL.	
	Examiner	Art Unit	
	Lisa J. Hobbs	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,15 and 18-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 15, 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 7, 15 and 18-22 are active in the case. Claims 1-6, 8-14 and 16-17 have been cancelled by amendment. Claims 7, 15 and 18-22 are under examination; no claims are withdrawn as drawn to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7, 15, and 18-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19 and 21-25 of copending Application No. 10/975367. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a method using a nucleotide vector comprising the same sequences; instant SEQ ID NO: 2 is identical to SEQ ID NO: 2 of

10/975367 and instant SEQ ID NO: 4 is identical to SEQ ID NO: 16 of 10/975367. The claims are directed to using identical polypeptides expressed from DNA vectors transfected into cells in method increasing insulin production, insulin content, and insulin-stimulatory signaling in the cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment made removing the word "homology" and substituting the word "identity".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7, with dependent claims 15 and 18-22, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what applicant intends to claim with the phrase "or a cell membrane thereof" which is recited in the independent claim after the listing of the Markush group of polypeptide possibilities; the modifier "thereof" does not relate directly to the three polypeptide possibilities directly preceding it and it is unclear what the metes and bounds of the claim are with the recitation of "cell membrane thereof" when the only

reference to a cell is placed before the recitation of the polypeptide elements presumably comprised a cell membrane. For the purposes of this examination, the examiner has moved the phrase so that the word "thereof" refers to the transformed cell. It has been placed above the Markush grouping, as follows:

:…bringing a cell transformed with an expression vector comprising a polynucleotide encoding a polypeptide and expressing the polypeptide, or a cell membrane thereof, in which the polypeptide is selected…".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7 and 19-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 7,108,991, issued 19 September 2006, which claims priority to provisional application 60/141,448, filed 29 June 1999).

Chen et al teach a method of using a G protein-coupled receptor called RUP3 in an assay for identifying compounds that modulate insulin production. RUP3 (also identified in the patent of Chen et al as SEQ ID NO: 8) is identical to instant SEQ ID NO: 2. Specifically, the RUP3 DNA is inserted into a DNA vector which is transfected into cells; the cells are then contacted with an agonist or antagonist that inhibits or stimulates insulin production (see Claims 1-11, for

example). The step of "confirming" recited in instant claim 7 is a step of repeating or measuring; one would expect the same results from the steps recited in Chen et al regardless of the number of times the assay is performed. As well, Chen et al. (claim 1) specifically recite a method "measuring the ability of the compound or compounds to inhibit or stimulate said receptor, wherein said inhibition or stimulation of said receptor is indicative of a compound for regulating insulin concentration in the blood of a mammal" thus one would be "confirming that the selected substance increases insulin production and/or content".

The step of using a promoter activity assay to determine increased function is disclosed by Chen et al. (col. 6, lines 44-61), who state that "[a]nother type of assay that can be utilized is a whole cell second messenger reporter system assay. Promoters on genes drive the expression of the proteins that a particular gene encodes. Cyclic AMP drives gene expression by promoting the binding of a cAMP-responsive DNA binding protein or transcription factor (CREB) which then binds to the promoter at specific sites called cAMP response elements and drives the expression of the gene. Reporter systems can be constructed which have a promoter containing multiple cAMP response elements before the reporter gene, e.g., .beta.-galactosidase or luciferase. Thus, a constitutively activated Gs-linked receptor causes the accumulation of cAMP that then activates the gene and expression of the reporter protein. The reporter protein such as .beta.-galactosidase or luciferase can then be detected using standard biochemical assays".

Therefore the teachings of Chen et al are deemed to anticipate instant claims 7, 15 and 19-20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable Chen et al. (US 7,108,991, issued 19 September 2006, which claims priority to provisional application 60/141,448, filed 29 June 1999).

Chen et al teach a method of using a G protein-coupled receptor called RUP3 in an assay for identifying compounds that modulate insulin production. RUP3 (also identified in the patent of Chen et al as SEQ ID NO: 8) is identical to instant SEQ ID NO: 2. Specifically, the RUP3 DNA is inserted into a DNA vector which is transfected into cells; the cells are then contacted with an agonist or antagonist that inhibits or stimulates insulin production (see Claims 1-11, for example). The step of "confirming" recited in instant claim 7 is a step of repeating or measuring; one would expect the same results from the steps recited in Chen et al regardless of the number of times the assay is performed. As well, Chen et al. (claim 1) specifically recite a method "measuring the ability of the compound or compounds to inhibit or stimulate said receptor, wherein said inhibition or stimulation of said receptor is indicative of a compound for regulating insulin concentration in the blood of a mammal" thus one would be "confirming that the selected substance increases insulin production and/or content" and selecting a substance which increases the promoter activity by 1.5 times or more, while not recited specifically, would be encompassed by the claim that any level of "inhibition or stimulation of said receptor is indicative of a compound for regulating insulin concentration in the blood of a mammal".

Chen et al. state that "[s]creening candidate compounds against an endogenous or non-endogenous, constitutively activated version of the human orphan GPCRs disclosed herein can provide for the direct identification of candidate compounds which act at this cell surface receptor, without requiring use of the receptor's endogenous ligand. By determining areas within the body where the endogenous version of human GPCRs disclosed herein is expressed and/or over-expressed, it is possible to determine related disease/disorder states which are associated with the expression and/or over-expression of the receptor; such an approach is disclosed in this

patent document." And "RUP3 is expressed within the human pancreas, suggesting that RUP3 may play a role in insulin regulation and/or glucagon regulation. Accordingly, candidate compounds identified using a constitutively activated form of RUP3 may be useful for understanding the role of RUP3 in diabetes and/or as therapeutics for diabetes" (col. 5).

The step of using a promoter activity assay to determine increased function is disclosed by Chen et al. (col. 6, lines 44-61), who state that "[a]nother type of assay that can be utilized is a whole cell second messenger reporter system assay. Promoters on genes drive the expression of the proteins that a particular gene encodes. Cyclic AMP drives gene expression by promoting the binding of a cAMP-responsive DNA binding protein or transcription factor (CREB) which then binds to the promoter at specific sites called cAMP response elements and drives the expression of the gene. Reporter systems can be constructed which have a promoter containing multiple cAMP response elements before the reporter gene, e.g., beta-galactosidase or luciferase. Thus, a constitutively activated Gs-linked receptor causes the accumulation of cAMP that then activates the gene and expression of the reporter protein. The reporter protein such as beta-galactosidase or luciferase can then be detected using standard biochemical assays".

Response to Arguments

Applicant's arguments filed 11 July 2008 have been fully considered but they are not persuasive. Applicants argue that Chen et al. do not fully recognize the functionalities of the RUP3 protein and its relationship to insulin, particularly that Chen et al. do not disclose that RUP3 promotes insulin increase merely disclosing that RUP3 plays a role in insulin "regulation". However, "regulation" could be either increasing or decreasing the amount of the compound of

interest, and both "increasing" and "decreasing" the amount of the compound of interest is disclosed by Chen et al. can be interpreted by one of skill as clearly indicative of medically important information; Chen et al. state, as discussed above, "it is possible to determine related disease/disorder states which are associated with the expression and/or over-expression of the receptor" (col. 5). Thus, "regulation" clearly encompasses increasing insulin.

Applicants argue that Chen et al. take no steps to measure insulin, however Chen et al. clearly state that one of skill may use reporter genes such as luciferase, as disclosed by applicants on p. 22, in conjunction with receptors/promoters to determine and quantitate a change in the amount of expression, including increased expression, of the receptor/promoter as a result of compounds which are added to test that receptor/promoter.

Also argued is that Chen et al. do not recite measurement of insulin as necessary in their screening method, however claim 1 recites "[a] method for identifying a compound for regulating insulin concentration in the blood of a mammal comprising the steps of: contacting one or more candidate compounds with a host cell that expresses a receptor comprising the amino acid sequence of SEQ ID NO: 8; and measuring the ability of the compound or compounds to inhibit or stimulate said receptor, wherein said inhibition or stimulation of said receptor is indicative of a compound for regulating insulin concentration in the blood of a mammal".

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday to Friday, 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh